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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO.       |
|---|-------------|----------------------|-------------------------------|------------------------|
| 10/542,184  | 02/06/2006  | Alun Davies          | PC19486A                      | 7850                   |
| 28940   | 7590        | 07/27/2007           |                               |                        |
| PFIZER INC<br>10555 SCIENCE CENTER DRIVE<br>SAN DIEGO, CA 92121 |             |                      | EXAMINER<br>HOWARD, ZACHARY C |                        |
|   |             |                      | ART UNIT<br>1646              | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>07/27/2007       | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                               |  |
|------------------------------|-------------------------------|-------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/542,184 | Applicant(s)<br>DAVIES ET AL. |  |
|                              | Examiner<br>Zachary C. Howard | Art Unit<br>1646              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of Application, Amendments and/or Claims*

Claims 1-32 are pending in the instant application.

### *Election of species*

Elections of species are required as follows. Applicants are requested to note that Part (I) requires two elections and Part (II) requires one election.

(I) This application contains claims directed to more than one species of NGF responsive genes of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of NGF responsive genes are as follows: spinocerebellar ataxia type 1 (sca1), substance P, lymphocyte antigen 86 (MD-1), Hippocampus cDNA homologue to Microsomal Signal Peptidase, Neuronal Leucine Rich Repeat Protein 1 (NLRR-1), Synaptotagmin V, Cadherin 1, EST weakly similar to KIAA0982, EST weakly similar to RIKEN cDNA 2310042NO2, small proline-rich repeat protein 1A (sprr1A), Motopsin (Neurotrypsin), Inhibin Beta B, G protein-coupled receptor 19, Lipocalin 2, Troponin C, and galanin.

Claims 1-26 are directed to methods wherein the level of expression of two or more NGF responsive genes are measured. Claims 27-30 are directed to methods wherein the level of expression of one or more NGF responsive genes are measured. As such, all claims encompass a method wherein two NGF responsive genes are measured.

Therefore, Applicants are required, in reply to this action, to elect two species of NGF responsive genes to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. **Importantly, for each of the two elected species, Applicants must identify whether or not each elected**

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**species is “enhanced” (such that claim 9 reads on the elected species) or “diminished” (such that claim 11 reads on the elected species) in the presence of NGF.**

An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each gene is a nucleic acid (DNA) encoding a corresponding nucleic acid (mRNA) and each pair (DNA and corresponding mRNA) is composed series of nucleotides that is structurally different from each other pair. Lack of unity is shown because these treatments lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

**(II) This application contains claims directed to more than one species of neurons of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.**

The species of neurons are as follows: nociceptive neurons of the Dorsal Root Ganglia, trigeminal ganglion nociceptive neurons, trigeminal ganglion non-nociceptive neurons, sympathetic neurons, Nerve Growth Factor responsive subpopulation of the nodose ganglia and basal forebrain cholinergic neurons.

Claims 1, 2, 5-20, 23-27 and 30-32 are generic.

Claim 3 recites each species a Markush-type group.

Claim 4 is limited to the species of nociceptive neurons of the Dorsal Root Ganglia.

Claims 21 and 28 are limited to those species that are nociceptive neurons.

Claims 22 and 29 are limited to nociceptive neurons of the Dorsal Root Ganglia or nociceptive neurons of the trigeminal neurons.

Therefore, Applicants are required, in reply to this action, to elect one species of neurons to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. **Importantly, Applicants must identify whether or not the elected species is a nociceptive neuron, such that it would be encompassed by claim 21 and 28.**

An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each type of neuron is found in a different tissue location in an organism, and each expresses a different pattern of genes, and therefore each is structurally different from the other types. Lack of unity is shown because these treatments lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646